REMARKS / ARGUMENTS

Claims 1 and 2 have been amended to clarify that the active ingredient is added to the auxiliary solvent if all of the active ingredient is not included in the powder or granulate component. Claim 13 has been amended to indicate that the solid dosage form dissolves rapidly in aqueous medium such as saliva in the mouth. Claims 14, 15, 18, 22, 24 and 26 have been amended to be dependent on claim 13. Claims 1-11 and 13-27 are currently pending.

Claims 13-26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Pat. No. 6,083,531 ('531) in view of US 4,311,490 ('490). The Examiner stated that the '531 patent does not claim the disintegrant, but the '490 patent discloses binder such as polymethylmethacrylate.

Applicants respectfully request reconsideration since there is no case of prima facie obviousness. The '490 patent is directed to an abrasive cutting tool, and it does not even teach any composition that can be ingested or even dissolved in aqueous medium. Given that the '490 patent is directed to an abrasive cutting tool whereas the present claims are directed to a pharmaceutical composition, there is no motivation to select an isolated teaching of a binder for an abrasive composition and combine with a pharmaceutical composition. Moreover, there cannot be any reasonable expectation of success. Applicants request reconsideration and withdrawal of the rejection since the present invention is not obvious over the '531 patent in view of the binder for the abrasive tool of the '490 patent.

Claims 1-11 were rejected under 35 U.S.C. 112, first paragraph. The Examiner stated that the active substance is critical or essential but is not included in step (a)(2). Applicants submit that claims 1 and 2 have been amended to indicate that when an active substance is not included in step (a), the active substance in added to the final composition by adding the active to the solvent, which is combined with the component of step (a) in a later step. Applicants submit that with the amendment, the rejection has been overcome, and request reconsideration of the rejection.

Claims 1-26 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner stated that claim 1 was lacking a proper antecedent basis and step a(2) may be lacking the active substance. As for claims 13-26, the Examiner stated that the claims were improperly dependent on a cancelled claim.

Applicants submit that independent claim 1 and claim 2 have been amended to indicate that the active substance is combined with an auxiliary solvent to form a solution or dispersion if not all of the active substance is used in step (a), the powder or granulate preparation step. Therefore, if the product of step (a) does not contain an active ingredient, the active ingredient is incorporated into the final product with the solvent. Accordingly, Applicants submit that the rejection covering claims 1-11 has been overcome. As for claims 13-26, claim 13 has been amended to be an independent claim and other dependent claims have been amended to properly dependent on claim 13. Applicants submit that the improper dependency has been correct. Applicants respectfully submit that the rejection covering claims 1-11 and 13-26 has been overcome and request withdrawal of the rejection.

Claims 1-11 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/38679 (WO679). The Examiner stated that although WO 679 does not teach compacting the prepared powder or granulate, the extra step does not impart a patentable distinction and it would have been prima facie obvious to modify WO679.

Applicants respectfully submit that the Examiner has not established a prima facie case of obviousness, and request reconsideration. The present invention is a highly different process of manufacturing a fast disintegrating oral dosage form than the one disclosed in WO679. As indicated by the Examiner, the present process has the step of producing a compacted powder or granulate. In addition, the present process has an additional step of placing the compacted powder or granulate in a solvent, such that the solvent is absorbed in to the compacted powder and granulate. The solvent is then removed from the compacted powder or granulate to produce a solid oral dosage form. In clear contrast, WO679 teaches a process that requires that all of the ingredients of the oral form is dissolved or suspended in a solvent first, and then the solution or suspension is placed in a mold to evaporate the solvent from the solution. There is no suggestion in WO679 that any compacted mass of the ingredient can be produced for any reason. In fact, it is a waste of efforts and it is illogical to produce a compacted mass of the ingredients first only to dissolve the compacted mass in the solvent to produce a solution or suspension when powder or granule of the same ingredients will be more easily dissolved or suspended in a solvent. One skilled in the art would not introduce the extra step of compacting the ingredient only to produce a solution or suspension when the mass will only increase the time to dissolve or suspend the same ingredients in a solvent. There is not only no motivation to do what is suggested by the Examiner, but also the suggested steps are only hypothetical possibilities that has no benefit but added steps and burdens. Applicants submit that a prima facie case of obviousness has not been established since the Examiner has not demonstrated any motivation to modify the process of WO679. Applicants respectfully request withdrawal of the rejection.

Claims 13-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO679 in view of Erodes et al. (Erodes). The Examiner stated that WO679 does not teach the disintegrant, but Erodes teaches auxiliary agents for a tablet dosage form.

Applicants respectfully submit that the Examiner has not established a prima facie case of obviousness. As indicated by the Examiner, WO679 does not teach disintegrants, and Erodes is directed to a tablet that has nothing to do with a fast dissolving tablet that is designed to quickly dissolve in the mouth. Accordingly, there is no motivation to selectively pick out a specific element from Erodes and combine with WO679. Such a modification can only be done using the teachings of the present invention, and such a hindsight modification is improper. Erodes is directed to a coated tablet that releases its active some time after the tablet is ingested. The tablet of Erodes has two portions - a quick release portion and a sustained release portion. Erodes teaches at column 2, lines 36 - 40, that even the quick release portion only releases 50% of the active ingredient in about one hour. Erodes does not teach anything about a fast dissolving tablet. Applicants submit that a prima facie case of obviousness cannot be established by merely picking and choosing elements from a secondary reference and combining with the primary reference without any motivation and expectation of success. Applicants request reconsideration and withdrawal of the rejection.

Claims 13-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO679 and US 4,311,490 ('490). The Examiner stated that the '490 patent teaches a binder such as polymethylmethacrylate, and the binder make the present invention obvious.

Applicants respectfully submit that a prima facie case of obviousness has not been established. As discussed above, the '490 patent is directed to an abrasive cutting tool. It cannot be expected that a binder suitable for an abrasive cutting tool to be suitable for a pharmaceutical composition. There is no motivation to combine the abrasive tool binder of the '490 patent to a pharmaceutical composition of WO679. Applicants respectfully submit that a prima facie case of obviousness has not bee established, and request reconsideration and withdrawal of the rejection.

In summary, Applicants submit that with the above amendment to the pending claims, the 35 U.S.C. 112, first and second paragraph, rejections have been overcome, and a prima facie case of obviousness has not been established. Applicants also submit that a case of the double patenting rejection has not been established. Applicants respectfully request reconsideration and withdrawal of the rejections set forth in the Office Action.

No additional fees other than the fee for petition for extension are believed due, however, the Commissioner is hereby authorized to charge any fees which may be required in connection with this response, or credit any overpayment to Deposit Account No. 19-0134.

Respectfully submitted,

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